SUPREME COURT, U.S.
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No. 78-421

In the Supreme Court of the United States

OCTOBER TERM, 1978

DAHLBERG ELECTRONICS, INC., ET AL., APPELLANTS

v.

GEORGE KIEVLAN, ET AL.

ON APPEAL FROM THE COURT OF APPEAL OF CALIFORNIA, FIRST APPELLATE DISTRICT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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This brief is filed in response to the Court's invitation of November 27, 1978.

QUESTIONS PRESENTED

1. Whether either the injunction against appellants or the state statute on which it is based restrains commercial speech in violation of the First Amendment.

2. Whether the state statute on which the injunction is based has been preempted by the Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*

STATUTES INVOLVED

Section 26460 of the California Health and Safety Code (West 1978 Cum. Supp.) provides:

> It is unlawful for any person to disseminate any false advertisement of any food, drug, device or cosmetic. An advertisement is false if it is false or misleading in any particular.

Section 26463 of the California Health and Safety Code (West 1978 Cum. Supp.) provides in pertinent part:

> It is unlawful for any person to advertise any drug or device represented to have any effect in any of the following conditions, disorders, or diseases:
>
> * * * * *
>
> (m) Diseases or disorders of the ear or auditory apparatus; including hearing loss and deafness.

Section 26465 of the California Health and Safety Code (West 1978 Cum. Supp.) provides:

> Whenever the [California Department of Health] determines that an advance in medical science has made any type of self-medication safe and effective as to any of the conditions, disorders, or diseases named in Section 26463, the department shall, by regulation, authorize the advertisement of any such drug or device as having a curative or therapeutic effect for such disease, subject to such conditions and restrictions as the department may consider necessary to the interests of public health.

Section 521(a) of the Food, Drug, and Cosmetic Act, 21 U.S.C. 360k(a), provides:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of of the device or to any other matter included in a requirement applicable to the device under this chapter.

STATEMENT

Appellants manufacture, advertise and sell hearing aids. Appellees, persons with impaired hearing, brought this suit against appellants in a California Superior Court seeking recission, damages and an injunction on the ground that appellants' advertisements were unlawful under Section 26463(m) of the California Health and Safety Code (J.S. Exh. B 37). The superior court found that the advertisements violated Section 26463(m) because they represented that appellants' hearing aids had an "effect in * * * [d]iseases or disorders of the ear or auditory apparatus, including hearing loss and deafness" within the meaning of the statute. The court rejected appellants' contention that Section 26463(m) prohibits only claims that hearing aids would have a curative effect on hearing disorders and does not prohibit claims that they would "merely compensate[ ] for the disorder or condition the way a prosthesis does for loss of a limb" (J.S. Exh. B 40). The court found no such distinction in the statute and enjoined appellants "from advertising their hearing aids in California by representing that said hearing aids have any effect on diseases or disorders of the ear, or auditory apparatus, including hearing loss and deafness" (*id.* at 44).

The Court of Appeal of California affirmed (J.S. Exh. A 28-36). Appellants argued in the court of appeal that the injunction, and Section 26463(m) on which it was based, violate the First Amendment because they prohibit appellants from making truthful claims about their hearing aids, *e.g.*, that they compensate for hearing loss. The court found it unnecessary to reach that claim, stating (J.S. Exh. A 31-32):

> The judgment enjoined [appellants] from advertising their hearing aids by representing that the hearing aids have any effect on diseases or disorders of the ear including hearing loss and deafness. The [California Health and Safety Code], section 26460,

> declares it is unlawful for any person to disseminate any false advertisement of any device and declares an advertisement is false if it is false or misleading in any particular. It is clear from the copies of the advertisements that are included in the record that the advertisements were misleading in that they convey the impression that the hearing aid would have a curative or therapeutic effect. The [appellants] in their brief concede that hearing aids do not have a curative or therapeutic effect. The *Virginia State Board of Pharmacy* [v. *Virginia Citizens Consumer Council, 425 U.S.* 748 (1976)] case is of no help to [appellants]. As a concurring opinion points out the court's decision did not preclude state and federal regulation of false or deceptive advertising. The injunction is thus proper.

The court also stated that the trial court correctly held that Section 26463(m) encompasses advertisements representing that hearing aids have a compensatory effect as well as those representing that they have a curative or therapeutic effect (J.S. Exh. A 30-31). Finally the court rejected appellants' argument that 21 U.S.C. 360k preempts Section 26463(m) of the California Health and Safety Code (J.S. Exh. A 32-34).

ARGUMENT

Appellants reiterate the arguments that they advanced in the California Court of Appeal: They maintain that Section 26463(m) and the injunction violate the First Amendment because they prohibit truthful advertisements and that Section 26463(m) is preempted by the Food, Drug, and Cosmetic Act. Appellants' arguments seem to us to misconceive the holding of the court of appeal.

As we read the court of appeal's opinion, the court held that the injunction prohibits only advertising claims that are false and misleading—*i.e.*, claims that appellants' hearing aids have a curative or therapeutic effect on hearing disorders (appellants conceded they have no such effect)—and that the injunction was therefore authorized by Section 26460 of the California Health and Safety Code. Given this conclusion, the court of appeal found it unnecessary to reach appellants' claim that the injunction and Section 26463(m) are unconstitutional. Because appellants do not contend that a state statute or injunction prohibiting false and misleading claims is unconstitutional or is preempted by federal law,[1] there is no properly presented federal question for this Court to consider. This Court reviews judgments, not opinions (*Herb* v. *Pitcairn*, 324 U.S. 117, 125-126 (1945)), and even if appellants' arguments about Section 26463(m) are

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[1]On the contrary, they concede the validity of Section 26460 (J.S. 21 n.9, 23). See also, *e.g.*, *Ohralik* v. *Ohio State Bar Assn.*, 436 U.S. 447 (1978); *Bates* v. *State Bar of Arizona*, 433 U.S. 350, 383 (1977). Section 26460 is not preempted by the Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, for that statute preempts only state statutes that impose any requirement "different from, or in addition to, any requirement applicable under this chapter." 21 U.S.C. 360k(a). Section 26460, which prohibits false or misleading advertising, is identical to a prohibition in the federal statute, which provides that a "restricted device" (which includes hearing aids) shall be deemed to be misbranded if "its advertising is false or misleading in any particular." 21 U.S.C. 352(q).

correct, there is simply nothing wrong with a judgment based, as this one is, on Section 26460.[2]

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[2]Although the court discussed the scope of Section 26463(m) and appeared to suggest that that section prohibits more than false or misleading advertising claims, that discussion is *dicta*. Moreover, it is not clear the court believed that Section 26463(m) prohibits advertising claims that are not false and misleading. The court of appeal, like the superior court, rejected appellants' contention that Section 26463(m) prohibits only claims that hearing aids will have a "curative or therapeutic" effect on hearing disorders (which appellants conceded would be false) but does not prohibit claims that hearing aids may have a "compensatory effect" on hearing disorders (which appellants claimed is true). But the term "compensatory effect" is ambiguous, and appellants seem to avoid defining it with precision. A spectrum of claims may be posited. The statement "our hearing aids will cure your deafness" is clearly a curative claim that appellants concede would be false. The statement "our hearing aids amplify sound" could be viewed as a "compensatory effect" claim and would presumably be true and not misleading. Closer questions, however, are presented by such claims as "our hearing aids will help you hear clearly" or "our hearing aids may help you hear clearly." It is not clear whether such claims would fall within appellants' "compensatory effect" category, or whether they could be viewed as implying a curative effect, or whether in any event they would be false or misleading in view of studies showing that many people with hearing disorders cannot be assisted by hearing aids. Since, in our view, the court of appeal held that the injunction prohibits only false and misleading claims, it is unnecessary to understand fully its views about the scope of Section 26463(m) or the meaning of appellants' "compensatory effect" theory. Whether particular claims that appellants may make in the future will be false and misleading and thus in violation of the injunction is not ripe for review and would turn, in any event, on the particular facts. Moreover, if appellants have any uncertainty in that respect, they may seek clarification from the superior court. Cf. *FTC* v. *Colgate-Palmolive Co.*, 380 U.S. 374, 394 (1965).

The court of appeal's conclusion that Section 26463(m) is not preempted by the Food, Drug, and Cosmetic Act (J.S. Exh. A 32-34) also is *dicta*. Whether that view was correct depends on whether the court believed that Section 26463(m) prohibits claims that are not false and misleading. If it believed that the section does prohibit truthful, non-misleading claims, then its conclusion that Section 26463(m) is not preempted is erroneous. Contrary to the court's belief (J.S. Exh. 34), hearing aids are classified by regulation as "restricted devices" within the meaning of 21 U.S.C. 352 and 360j(e)(1) (see 21 C.F.R. 801.420 *et seq.*). 21 U.S.C. 352(r) permits advertisements of restricted devices if they include "a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications * * *," and 21 U.S.C. 360k(a) preempts any more stringent state law. The Secretary has not excepted Section 26463(m) from preemption under the provisions of 21 U.S.C. 360k(b).

CONCLUSION

The appeal should be dismissed for want of a properly presented federal question.

Respectfully submitted.

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